## Remarks

The Examiner has, again, rejected claims 1-15 and 17 under 35 U.S.C. § 103(a) as being unpatentable over European Patent Application No. EP 0722980 to Bastioli *et al.* (hereinafter "Bastioli '980") in view of the journal article "Biodegradeable blends of cellulose acetate and starch: ...," by Mayer *et al.* (hereinafter "Mayer"), and Japanese Unexamined Patent Laid Open Application No. JP 07102114 (hereinafter "JP '114"). (See Paper No. 10 at 2). For the reasons presented below, reconsideration and withdrawal of the rejection respectfully is solicited.

The Examiner in Paper No. 10 maintained the obviousness rejection presented in Paper 7 and also included a terse commentary discussing applicants' Response to the § 103 rejection filed September 20, 2002. Below are some excerpts from the Examiner's original § 103 rejection found in Paper 7.

With regard to Bastioli '980, the Examiner asserted that:

> "[Bastioli] discloses biodegradeable compositions comprising (a) starch, (b) a cellulose ester or ether, (c) a plasticizer for starchy phase, cellulose and derivatives and (d) and compatibilizer agent (abstract). Starch and cellulose are present in a range from 1:90 to 90:1 by wt (p. 10, lines 31-33). Plasticizer is present from 5-40% by wt (p. 10, line 55 to p. 11, line 1). Compatabilizing agents described on page 2, lines 31-50 read on those encompassed by instant claims 9-11. Various articles can be moulded. (p.2, lines 20-22).
> Bastioli does not mention an additive (of instant claim 1). (Paper No. 7 at.4)."

To fill the acknowledged gap, the Examiner relied on Mayer for disclosing:

> biodegradable blends of [cellulose] acetate and starch. Degree of substitution of cellose acetate should be 2.5 or less (p.776, 3rd papragraph). In expensive [sic] are added to the blends. (Paper No. 7 at 4).

The Examiner further relied on JP '114 for disclosing:

> biodegradable composition containing cellulose ester, starch and plasticizer together with an additive like talc, calcium carbonate, magnesium carbonate etc. (Paper No. 7 at 4).

Finally, the Examiner concluded by asserting that:

> it would have been obvious to add to the composition of [Bastioli], carbonates and hydroxides of calcium and magnesium in order to reduce the cost of production, without affecting quality and performance. It would also have been obvious to use cellulose ester i.e. polysaccharide of degree of substitution of not more than 2.5 in order to maintain good biodegradability of the composition. (Paper No. 7 at 4).

In the Final Office Action (Paper 10), the Examiner stated that "[a]pplicants' argument (page 7) that JP '114 does not teach [the] role of additives to regulate pH is not persuasive ***since it is reasonable to assume that additives of JP '114 do improve strength and also regulate pH***." (Paper No. 10 at 2) (emphasis added). The Examiner further stated that "[a]pplicants' arguments based on amounts of plasticizer taught by [the] prior art are also not persuasive. It is within the expertise of one to vary the amounts to achieve optimum results." *Id.*

Initially, we note that the Examiner's burden for making a prima facie case of obviousness, in accordance with MPEP § 706.02(j), is as follows (emphasis and numbers added):

> To establish a prima facie case of obviousness, three basic criteria must be met. (1) First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. (2) Second, there must be a reasonable expectation of success. (3) Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure* . . . .

> The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references."

The Federal Circuit has made clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references and that such references can be combined only if there is some suggestion or incentive to do so. *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Here, the rejection fails to identify ***why*** one skilled in this art would modify the disclosure of Bastioli '980 and Mayer using JP '114 to arrive at the claimed invention. The Examiner in rejecting claims 1-15 and 17 stated "***it is reasonable to assume***" that one of ordinary skill in the art would have added the additives of JP '114 to the composition of Bastioli '980 to "*improve strength* ***and also regulate pH***" without providing any factual support as to ***why*** it is reasonable to assume this. This is a clear gap in the Examiner's reasoning. When a conclusion of obviousness is not based upon facts or factual support, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). For this reason alone, the rejection should be withdrawn.

As stated above, in order for references to be properly combined, there must be a suggestion or motivation in the references to combine them. <u>See also</u>, *In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988). No such suggestion exists in the references cited by the Examiner, and the Examiner does even contend that the requisite suggestion exists. Instead, the Examiner remarks that "it would have been obvious to add to the composition of [Bastioli], carbonates and

hydroxides of calcium and magnesium in order to reduce the cost of production, without affecting quality and performance" (Paper 7 at 4) and "it is reasonable to assume that additives of JP '114 do improve strength and also regulate pH" (Paper 10 at 2). Yet, the rejection identifies no *disclosure* in Bastioli '980, Mayer, or JP '114 that *suggests* adding the additives of JP '114 to the composition of Bastioli '980. Contrary to the Examiner's "***reasonable to assume***" argument for obviousness, no such rule of law exists, and the Examiner has not cited any authority for his *per se* rule of what is *prima facie* obvious. It is well settled that there are no *per se* rules of patentability (*see* MPEP § 2116.01 at 2100-52; and *see also* the Commissioner's Notice at 1184 OG 86).

Simply put, Bastioli '980 does not disclose or suggest that adding a "pH-raiser" as an additive would increase the biodegradability of the claimed compositions. The compositions of Bastioli '980 are endowed with an improved biodegradability because of a high dispersion of starch in the cellulose acetate matrix, but the decomposition rate of the articles are still **slow** compared to the compositions of the present invention. (See Specification, p. 1, last two paragraphs and Comparative Examples 1-4).

The Examiner cites JP '114 and cites the above reasons as the alleged motivation to combine the references. However, JP '114 does not suggest that the additives disclosed would be useful for regulating pH (or for increasing the biodegradability of the composition) or that even some of the additives would be useful for regulating pH. The record is devoid as to ***why*** it would have been "reasonable to assume" that some of the numerous additives of JP '114 can be pH regulators, let alone "pH raisers," or biodegradability enhancers. The Examiner has not cited disclosure in any of the cited references even hinting at such. Obviousness cannot be based upon

*speculation*, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970).

The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *Lee*, 61 USPQ2d at 1433 (emphasis added). The search for and analysis of the prior art by the Examiner must include *evidence relevant* to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001).

Moreover, the Examiner has overlooked a crucial point in JP '114. The Examiner stated that "[a]pplicants' arguments based on amounts of plasticizer taught by [the] prior art are also not persuasive" because "[i]t is within the expertise of one to vary the amounts to achieve optimum results." (Paper No. 10 at 2). But "vary[ing] the amounts to achieve optimum results" is not the issue here. JP '114 discloses that the biodegradability of the compositions can be improved only when the plasticizer is used in proportions of 55% and 63% to the total weight of the composition (experiments 2 and 3 of Table 1). However, when the plasticizer is used in proportion of 47% and 33% (see Table 1, experiments 1 and 6) - that is, outside the range where improvement in biodegradability is seen - the biodegradability is reduced. Similarly, when the plasticizer is used in proportion of 33% and 41% (see Table 2, experiments 7-13), the biodegradability is even worse, *e.g.*, part of the filament was undamaged.

The amount of plasticizer used in the compositions of Bastioli '980 is only of 4% to 40% wt of the total composition, well outside the range disclosed by JP '114 as being useful in improving biodegradability. As a result, one of ordinary skill in the art would not have

considered the compositions of Bastioli '980 to be suitable candidates for us with any of the additives of JP '114, let alone calcium and/or magnesium carbonate specifically. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *See* MPEP § 2141.02. Because JP '114 teaches away, *i.e.*, teaches that when the plasticizer is used in the amounts disclosed in Bastioli '980 biodegradability is poor to possibility even undetectable, the rejection, for this additional reason, should be withdrawn. One of skill in the art reading JP '114 would not have expected any effect on the biodegradability of the compositions of Bastioli '980 by adding the additives of JP '114.

Before a conclusion of obviousness can be reached, the Examiner must demonstrate, with factual evidence, that one of ordinary skill in this art would have had ***a reasonable expectation*** that the combination alleged to be suggested by that art ***would be successful at the time the invention was made and in view of the prior art***. *See* MPEP § 2143.02 at 2100-126. The reasonable expectation of success is also judged in view of negative motivation (*e.g.*, skepticism of experts, and motivation that leads away from the subject matter claimed). In *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531-32 (Fed. Cir. 1988), a case involving polymerization products, the Court explained:

> The consistent criterion for determination of obviousness is whether the prior art would have ***suggested*** to one of ordinary skill in the art ***that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art...Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.***
>
> In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered; for the person of ordinary skill is charged with knowledge of the entire body of technological literature, ***including that which might lead away from the***

> ***claimed invention.*** The Commissioner argues that since the PTO is no longer relying on Farmer or the Bacon and Farmer article, the applicant is creating a "straw man." It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered.
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> The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. *Interconnect Planning Corporation v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). Of the many scientific publications cited by both Dow and the PTO, ***none suggests that any process could be used successfully*** in this three-component system, to produce this product having the desired properties. The skepticism of an expert, expressed before these inventors proved him wrong, is entitled to fair evidentiary weight, *see In re Piasecki,* 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed. Cir. 1984); *In re Zeidler,* 682 F.2d 961, 966, 215 USPQ 490, 494 (CCPA 1982), as are the five to six years of research that preceded the claimed invention. The evidence as a whole does not support the PTO's conclusion that the claimed invention would have been obvious in terms of *35 U.S.C. § 103.*

As demonstrated above, neither of the references disclose, teach, or suggest a reasonable expectation of success for increasing biodegradability rate using the claimed compositions. *See also In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). This point alone renders the Examiner's reasoning for combining the references in the Final Rejection untenable.

Furthermore, the problem addressed by the presently claimed invention is to improve the biodegradability rate of the Bastioli '980 compositions and *not* to improve the "strength" of the composition, which the additives disclosed in JP '114 focus on. In addition, the problem of increasing biodegradability of the compositions of Bastioli '980 and the compositions of JP '114 is achieved by different methods. The Examiner, therefore, has chosen parts of the

references to combine and parts not to combine using hindsight, which is an improper obviousness analysis as a matter of law. *See Fine*, 5 USPQ2d at 1600.

In summary, (1) the function of the additive in the present invention and in JP '114 is completely different; (2) increasing the biodegradability of the claimed compositions, the compositions of Bastioli '980, and the compositions of JP '114 are achieved by different methods; and (3) the amounts and ratios of cellulose ester, starch, and plasticizer for the compositions of the present invention compared to those of JP '114 differ so greatly that one of skill in the art would not be motivated to modify Bastioli '980 with the additives of JP '114 or have a reasonable expectation of success if they did modify Bastioli '980 with the additives of JP '114.

Therefore, the Examiner's assertion that one skilled in the art would have combined these references to arrive at the compositions of the presently claimed invention is factually and legally wrong.

Accordingly, for the above reasons, it is respectfully submitted that the Examiner's obviousness rejection be withdrawn.

## CONCLUSION

In view of the foregoing, favorable action on the merits, including withdrawal of the rejection, and allowance of all the claims, is respectfully requested. If the Examiner has any questions regarding this paper, please contact one of the undersigned attorneys.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 11, 2003.

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